Food and Drug Administration, HHS

- (c) Conditions of use in dogs—(1) Amount. Rub into affected areas two to four times daily for 4 to 10 days.
- (2) Indications for use. For topical treatment of allergic dermatitis and summer eczema.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 73 FR 79318, Dec. 29, 2008]

§524.2482 Triamcinolone spray.

- (a) Specifications. Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.
- (b) Sponsor. See No. 067292 in \$510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).
- (2) Indications for use. For the control of pruritus associated with allergic dermatitis.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 4916, Jan. 31, 2003]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

- (a)(1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.
- (2) Sponsor. See No. 051079 in \$510.600(c) of this chapter.
- (b)(1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.
- (2) *Sponsor*. See No. 017135 in §510.600(c) of this chapter.
- (c) Conditions of use. The drug is used as an aid in the treatment of external wounds and assists healing by facili-

tating the removal of necrotic tissue, exudate and organic debris.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 56307, Dec. 28, 1976; 50 FR 9800, Mar. 12, 1985; 54 FR 25565, June 16, 1989; 56 FR 37474, Aug. 7, 1991; 66 FR 46369, Sept. 5, 2001; 72 FR 36595, July 5, 2007]

PART 526—INTRAMAMMARY DOSAGE FORMS

Sec.

F00.00		4 11 1 4	c
		trihydrate	for
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526.1130) Hetacillin	potassium	for
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forms.			
526.1696a Penicillin G procaine.			
526.1696b Penicillin G procaine-dihydro-			

526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

526.1696d Penicillin G procaine-novobiocin for intramammary infusion. 526.1810 Pirlimycin.

AUTHORITY: 21 U.S.C. 360b.

§ 526.88 Amoxicillin trihydrate for intramammary infusion.

- (a) Specifications. Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.
- (b) *Sponsor*. See No. 000061 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.38 of this chapter.
- (d) Conditions of use—Lactating cows—(1) Amount. One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.
- (2) Indications for use. For the treatment of subclinical infectious bovine mastitis due to Streptococcus agalactiae

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and *Straphylococcus aureus* (penicillin sensitive).

(3) Limitations. Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§526.313 Ceftiofur.

- (a) Specifications. Each single-use, 10-milliliter syringe of ceftiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg ceftiofur equivalents.
- (b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.113 of this chapter.
- (d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (e) Conditions of use in cattle—(1) Lactating cows—(i) Amount. Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.
- (ii) Indications for use. For the treatment of clinical mastitis in lactating dairy cattle associated with coagulasenegative staphylococi, Streptococcus dysgalactiae, and Escherichia coli.
- (iii) Limitations. Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day pre-slaughter withdrawal period is required.
- (2) Dry cows—(i) Amount. Infuse 500 mg per affected quarter at the time of dry off.
- (ii) Indications for use. For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with Staphylococcus aureus, Streptococcus dysgalactiae, and Streptococcus uberis.

(iii) Limitations. Milk taken from cows completing a 30-day dry off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day pre-slaughter withdrawal period is required for treated cows. Following label use, no preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005. Redesignated and amended at 71 FR 39545, July 13, 2006]

§526.363 Cephapirin benzathine.

- (a) Specifications. Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.
- (b) *Sponsor*. See No. 000856 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.115 of this chapter.
- (d) Conditions of use—(1) Amount. Infuse contents of one syringe into each infected quarter.
- (2) Indications for use. Use in dry cows for treatment of mastitis caused by susceptible strains of Streptococcus agalactiae and Staphylococcus aureus, including penicillin-resistant strains.
- (3) Limitations. Infuse each infected quarter following last milking or early in the dry period, but no later than 30 days before calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. For use in dry cows only.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988; 73 FR 12262, Mar. 7, 2008]

§ 526.365 Cephapirin sodium.

- (a) Specifications. Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanutoil gel.
- (b) Sponsor. See No. 000856 in \$510.600(c) of this chapter.
- (c) Related tolerances. See §556.115 of this chapter.
- (d) Conditions of use in lactating cows—(1) Amount. Infuse one dose into each infected quarter immediately